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| APPLICATION NO.                   | FILING DATE        | FIRST NAMED INVENTOR            | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-----------------------------------|--------------------|---------------------------------|-------------------------|------------------|
| 10/511,700                        | 10/15/2004         | Monica Petronella Maria De Maat | 101137-56               | 2836             |
| 27387                             | 7590 11/27/2006    |                                 | EXAMINER                |                  |
| NORRIS, MCLAUGHLIN & MARCUS, P.A. |                    |                                 | SAUCIER, SANDRA E       |                  |
| 875 THIRD A                       | - · <del></del>    |                                 | ART UNIT                | PAPER NUMBER     |
| NEW YORK                          | NEW YORK, NY 10022 |                                 |                         |                  |
|                                   |                    |                                 | DATE MAILED: 11/27/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)   |  |  |  |  |
|--|---|--|--|--|--|--|
| Office A - Air - Commence  | 10/511,700  | DE MAAT ET AL.   |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit   |  |  |  |  |
|  | Sandra Saucier  | 1651   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONEI | l.<br>ely filed<br>the mailing date of this communication.<br>D (35 U.S.C. § 133). |  |  |  |  |
| Status   |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on   |   |  |  |  |  |  |
| ·= · ·   | action is non-final.  |  |  |  |  |  |
| <u>/</u>   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |  |  |  |  |  |
| Disposition of Claims  | ·   |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-24</u> is/are pending in the application.  |   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |  |  |  |  |  |
| 6)☐ Claim(s) is/are rejected.  |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |  |  |  |  |  |
| 8) Claim(s) <u>1-24</u> are subject to restriction and/or e  | lection requirement.  |  |  |  |  |  |
| Application Papers   |   |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |   |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |  |  |  |  |  |
| application from the International Bureau  | 1 11  |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |  |  |  |  |  |
|  |   |  |  |  |  |  |
|  |   | ·  |  |  |  |  |
| Attachment(s)  | -   |  |  |  |  |  |
| 1) Untice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date   |   |  |  |  |  |  |
| B) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application   |   |  |  |  |  |  |
| Paper No(s)/Mail Date 6)  Other:   |   |  |  |  |  |  |

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## DETAILED ACTION Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 3.1 and 37 CFR 1.475.

In accordance with these rules, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9, 11-13, drawn to a first method, a method of making a fibrin matrix using a fibrinogen variant or a fibrinogen enriched or depleted in a fibrinogen variant.

Group II, claim 10, drawn to a second method, a method of use of a fibrin matrix comprising a fibrinogen variant or a fibrinogen enriched or depleted in a fibrinogen variant.

Group III, claims 14-19, drawn to a pharmaceutical composition comprising fibrinogen and carrier, where the fibrinogen is a variant or a fibrinogen enriched or depleted in a fibrinogen variant.

Group IV, claims 20-24, drawn to a kit comprising fibrinogen variant or a fibrinogen enriched or depeleted in a fibrinogen variant.

(a) An international or national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those invention involving one or more of the same or corresponding special technical features. The expression "special technical

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features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. (b) An international or a national stage application containing claims to

- different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
- (1) a product and a process specially adapted for the manufacture of said product; or
  - (2) a product and a process of use of said product; or
- (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) a process and an apparatus or means specifically designed for carrying out said process; or
- (5) a product, a process specially adapted for the manufacture of the said product and an apparatus or means specifically designed for carrying out said process.
- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

None of groups of invention fall within any of the above categories.

The pharmaceutical composition of Group III comprises a carrier which is not required in the composition used in Group I nor the composition made in Group II, nor the kit of Group IV.

PCT Rule 13.2 does not provide for multiple compositions or multiple methods of use or making within a single application. Thus, the additional composition and method claims each constitute a separate group.

## **ELECTION OF SPECIES**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because

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they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: (a) fibrinogen consisting of HMW fibrinogen or (b) LMW fibrinogen or (c) LMW' fibrinogen or (d) Fib420 fibrinogen or (e) gamma' fibrinogen.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The following claims are generic: 1, 10, 14, 20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: fibrinogen variants are known in the prior art and fibrinogen variants have distinct molecular weights and distinct properties in the coagulation process, for example, HMW and LMW fibrinogen differ in clotting rate and fibrin polymerization characteristics.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (571) 272-0926. The normal work schedule for Examiner Saucier is 8:30 AM to 6:00 PM Monday and Tuesday and 8:30 AM-12:30 PM on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The number of the Fax Center for the faxing of official papers is (571) 272-8300.

Sandra Saucier

**Primary Examiner** 

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November 21, 2006